REMARKS

Applicants have carefully considered the Examiner's Non-Final Office Action, and respectfully request reconsideration of this Application in view of the above Amendment and the following remarks.

(a) Pending in this Application are Claims 1-20 and 36; and

(b) Claims 1-20 and 36 are claims the have been selected by the Applicants indicated in the restriction election requirement.

(c) Claims 21-35, 37 and 38 have been withdrawn from further considerations as being drawn to a non-elected invention as indicated in the restriction election requirement;

Amendments to Claims:

The Amended claims find support throughout the specification, including the following sections:

Claim 1-5, 7, 11, 12, and 36	Page 5, lines 24-30; Page 10, lines 7-20; and Page 11, lines 15-40; and Page 12, lines 16-30; Page 16 table 2; Page 17, lines 26-31 and elsewhere throughout the original claims and specification;
Claim 12-15, 18, and 20	Page 5, lines 24-30; Page 10, lines 7-20; and Page 11, lines 15-40; and Page 12, lines 16-30; Page 15, lines 3-14; Page 16 table 2; Page 17, lines 26-31 and elsewhere throughout the original claims and specification;

I. Rejections Under 35 U.S.C. §112 Second Paragraph

The Examiner has rejected Claims 1-20 and 36 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the subject matter which the applicant regards a the invention.

Rejection of Claim 1: The Examiner maintains that Claim 1 is vague because it is not clear as to what level of saposin indicates the presence of the lysosomal storage disorder. Additionally, the Examiner has indicated that Claim 1 is not clear as to what levels of saposin are involved in the monitoring of the lysosomal storage disorder.

In response, the Applicants have amended Claim 1 to address each of the Examiners concerns. Claim 1 now describes the levels and types of saposins involved in diagnosing or monitoring the presence of a lysosomal storage disorder in a patient. Support can be found in the specification on Page 5, lines 24-30; Page 10, lines 7-20; and Page 11, lines 15-26.

Rejection of Claim 11 and 12: The Examiner maintains that Claims 11 and 12 are vague because they are not clear as to what level of saposin indicates a progression of the disorder. The Examiner is also of the opinion that the claims are not clear as to what level of saposin and/or which saposin is correlated to each of the lysosomal storage disorders.

In response, the Applicants have amended Claims 1, 11 and 12 to address each of the Examiners concerns, please see amended claims above. Claims 1, 11 and 12 now indicate the levels and types of saposins involved in monitoring the progression of the disease or the response to treatment in a patient. Support can be found in the specification on Page 5, lines 24-30; Page 10, lines 7-20; Page 11, lines 15-40; and Page 12, lines 16-30.

Rejection of Claim 7: The Examiner is of the opinion that either the term "%" or "percentile" should be removed as it is confusing. Additionally, the Examiner believes that Claims 7 is indefinite since is not clear as to what a measured level that is greater than the 95% in a control population indicates.

In response, the Applicants have amended Claim 7 to contain the term "95th percentile." However, the Applicants respectfully disagree with the Examiners assertion on the clarity of using the term 95th percentile to indicate a measured level in a control population of a diagnostic assay. In this field it is customary to use percentiles to describe the separation of control and potentially affected groups, as is indicated in the specification on Page 10, lines 15-20; Page 11, 22-25; Page 16 table 2; Page 17, lines 26-31 and elsewhere throughout the specification.

Turning now to the merits of the claims, the Applicant's invention provides a method of diagnosing or monitoring a lysosomal storage disorder from a sample in a patient by measuring a level of at least a one saposin in a sample of obtained from the patient, wherein the level of saposin is similar or different from a baseline level of saposin determined in a control population of patients that are unaffected by the lysosomal storage disorder. Using the level of one or more saposins from an easily obtainable sample of plasma, serum, whole blood, urine, or amniotic fluid sample as an indicator of presence or extent of the lysosomal storage disorder in a patient is unique.

II. Rejections Under 35 U.S.C. §102(b)

A. Claims 1, 4, 7, 13-15, 17 and 18 stand rejected under 35 U.S.C. §102(b) over the O'Brien '1991 Reference. In response, Claims 1, 4, 7, 13-15, 17 and 18 now recite that the samples used for a method of diagnosing or monitoring are plasma, serum, whole blood, urine, or amniotic fluid in origin. This recited limitation is not disclosed or suggested in the O'Brien '1991 Reference, wherein the only samples mentioned are brain, liver and spleen. More specifically, measuring the saposin levels from a biopsy or repeated biopsies of a patients brain, liver, or spleen, as illustrated in the O'Brien '1991 Reference, is not realistic or practical for a diagnostic screening method. Because the O'Brien '1991 Reference cannot meet the limitation of the type of sample used, it is respectfully submitted that Claims 1, 4, 7, 13-15, 17 and 18 are now clearly and patentably distinguishable over the O'Brien '1991 Reference.

B. Claims 1-4, 7-10, 13-15, 17, 18, and 19 stand rejected under 35 U.S.C. §102(b) over the Chang '2000 Reference. The Chang '2000 Reference was published in the year 2000, and is

the Applicants published paper based upon the Applicant's current Application. The current Application is a 371 National Phase submission of PCT Application AU00/00193, which claims benefit of the United States Provisional Application 60/124,864 filed on March, 17, 1999. Thus, the Chang '2000 Reference was published after the earliest priority date of the current application and cannot be used as a basis for a 35 U.S.C. §102(b) rejection.

III. Rejections Under 35 U.S.C. §103(a)

A. Claims 5, 6, 11, 12, 20, and 36 stand rejected under 35 U.S.C. §103(a) over the Chang '2000 Reference. The Chang '2000 Reference was published in the year 2000, and is the Applicants published paper based upon the Applicant's current Application. The current Application is a 371 of PCT Application AU00/00193, which claims benefit of the United States Provisional Application 60/124,864 filed on March, 17, 1999. Thus, the Chang '2000 Reference was published after the earliest priority date of the current application and cannot be used as a basis for a 35 U.S.C. §103(a) rejection.

B. Claim 16 stand rejected under 35 U.S.C. §103(a) over the O'Brien '1991 Reference in view of the Stastny '1992 Reference as stated:

"O'Brien discloses the invention substantially as claimed, except for the antibody being a monoclonal antibody."

In order to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The rejection of Claim 16 is respectfully traversed for the following reasons. Claim 16 is a dependant on Claim 1, which now recites that the limitation of the samples used for a method of diagnosing or monitoring comprise: plasma, serum, whole blood, urine, or amniotic fluid. As previously discussed, the recited sample limitation of is not disclosed or suggested in the O'Brien '1991 Reference. Additionally, the Stanstny '1992 reference does not disclose or suggest the recited sample limitation of plasma, serum, whole blood, urine, or amniotic fluid in origin as stated in the amended Claim 16. Because all of the claim limitations are not taught or suggested, it is thus respectfully submitted that Claim 16 is allowable over the O'Brien '1991 Reference in view of the Stastny '1992 Reference, whether taken singly or in any combination thereof.

CONCLUSION

Applicants respectfully submit that, in light of the foregoing Amendments and comments, Claims 1-20 and 36 are all in condition for allowance. A Notice of Allowance is therefore requested for all claims. If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

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